Policy Statement

Computed tomography colonography (CTC) may be considered medically necessary for any of the following conditions:

- In patients for whom a conventional colonoscopy is indicated, but who are unable to undergo conventional colonoscopy for medical reasons (see Policy Guidelines section)
- In patients with an incomplete conventional colonoscopy because of colonic stenosis or obstruction
- In patients for the purposes of colon cancer screening

Except for the indications outlined in the policy statements above, CTC is considered investigational.

Policy Guidelines

Based on the currently available evidence, a colon cancer screening strategy using computed tomography colonography (CTC) is likely to produce outcomes similar to those with optical colonoscopy. Therefore, the “least costly alternative” provision of the medically necessary definition may apply (see Benefit Application section).

Computed tomography colonography (CTC) outcomes described in the literature represent outcomes under ideal conditions. This generally involves a comprehensive colon cancer screening program that includes rapid access to optical colonoscopy when necessary and systematic follow-up and surveillance of patients who generally have a more complicated follow-up schedule than do patients undergoing optical colonoscopy. Therefore, to achieve outcomes described in the literature that are similar to optical colonoscopy, CTC needs to be offered as part of a comprehensive colon cancer screening program that optimizes follow-up of patients undergoing this procedure.

Coding

There are category I CPT codes for this procedure:

- **74261**: Computed tomographic (CT) colonography, diagnostic, including image post processing; without contrast material
- **74262**: Computed tomographic (CT) colonography, diagnostic, including image post processing; with contrast material(s) including non-contrast images, if performed
- **74263**: Computed tomographic (CT) colonography, screening, including image post processing

CTC should be performed with a minimum 16-row detector computed tomography scanner.

Having adequate training was an important component of CTC clinical trials.

Contraindications to conventional colonoscopy may include continuous anticoagulation therapy or high anesthesia risk.

Description

Computed tomography colonography (CTC), also known as virtual colonoscopy, is an imaging modality of the colon that has been investigated as an alternative to conventional endoscopic (“optical”) colonoscopy. It has been most widely studied as an alternative screening technique for colon cancer, and for the diagnosis of colorectal cancer (CRC) in people with related symptoms and for other colorectal conditions.
Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Multiple computed tomography devices, including multiple CTC devices, have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Food and Drug Administration product code: JAK.

Rationale

Background

Computed tomography colonography (CTC), also known as virtual colonoscopy, is an imaging modality of the colon that uses thin-section helical computed tomography to generate high-resolution 2-dimensional axial images of the colon. Three-dimensional images, which resemble the endoluminal images obtained with conventional endoscopic colonoscopy, are then reconstructed offline. CTC has been investigated as an alternative to conventional endoscopic (“optical”) colonoscopy. While CTC requires a full bowel preparation, similar to conventional colonoscopy, no sedation is required, and the examination is less time-consuming. However, the technique involves gas insufflation of the intestine, which may be uncomfortable to the patient, and training and credentialing of readers may be needed to achieve optimal performance.

Indications

Diseases of the colon and rectum for which CTC may be considered as a diagnostic or screening tool include colorectal cancer and precancerous conditions, diverticulosis and diverticulitis, and inflammatory bowel disease. The most widely studied use of CTC is as an alternative screening technique for colon cancer.

Literature Review

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility demonstrating that the diagnostic information can be used to improve patient outcomes.

Computed Tomography Colonography for Colon Cancer Screening

Screening for colon cancer prevents morbidity by detecting early colon cancers and detecting and removing cancer precursors such as polyps. The detection of cancer and removal of polyps initially or ultimately require an optical colonoscopy. Computed tomography colonography (CTC) is an imaging procedure that can identify cancers or polyps. The effectiveness and efficiency of CTC depends on its ability to identify cancer or polyps accurately, so that all or
most patients who have such lesions are appropriately referred for colonoscopy for diagnosis and treatment and that polyps or cancer are not falsely identified.

**Clinical Validity**

**Systematic Reviews**
The diagnostic characteristics of CTC as a colon cancer screening test have been investigated in many studies in which patients referred for optical colonoscopy agree first to undergo a CTC. Using a second-look unblinded colonoscopy aided by the results of the CTC as the reference standard, the diagnostic characteristics of CTC and the blinded colonoscopy can be calculated and compared. The sensitivity of CTC is a function of the size of the polyp; sensitivity is poorer for smaller polyps. A 2004 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment found variable sensitivity and specificity of CTC at that time, with many studies showing poor sensitivity.¹

Several subsequent systematic reviews of studies on CTC in a colorectal cancer (CRC) screening setting have been published. Most recently, in 2016, Lin et al published a systematic review and meta-analysis of the literature on CRC screening, conducted for the U.S. Preventive Services Task Force (USPSTF).² Reviewers identified 9 prospective diagnostic accuracy studies on CTC (total N=6497 patients). Seven studies involved CTC with bowel preparation and two involved CTC without bowel preparation. Five studies, including both without bowel preparation, were rated by USPSTF as good quality and the remaining four were considered fair quality. In 4 studies of CTC with bowel preparation, the sensitivity to detect adenomas 6 mm or larger ranged from 73% to 98% and the specificity ranged from 89% to 91%. The sensitivity of CTC to detect adenomas 10 mm or larger (7 studies) ranged from 67% to 94%, and the specificity ranged from 96% to 98%. Four (n=481) of the 9 studies also provided data on colonoscopy. The sensitivity for adenomas 6 mm or larger ranged from 75% to 93%, and the sensitivity to detect adenomas 10 mm and larger ranged from 89% to 98%.

In addition, the Lin systematic review evaluated evidence on harms and extracolonic findings associated with CTC. Eleven fair or good quality prospective studies (total N=10,272 patients) suggested little or no risk of serious adverse effects such as perforation. In contrast, Lin et al estimated that, with optical colonoscopy, the risk of perforation was 4 in 10,000 procedures (95% confidence interval [CI], 2 to 5 in 10,000) and the risk of major bleeding was 8 in 10,000 procedures (95% CI, 5 to 14 in 10,000). Radiation exposure is a potential harm of CTC, but many of the studies did not report the extent of radiation exposure. Using data from 4 studies, Lin estimated that the radiation dose of a full-screening CTC examination was 4.5 to 7 mSv. However, in more recent studies (i.e., published between 2004 and 2008), the estimated radiation dose was lower, at 1 to 5 mSv. Among studies reporting this outcome, extracolonic findings occurred in 27% to 69% of CTC examinations. Approximately 1% to 11% underwent diagnostic evaluation, and 3% required treatment. Extracolonic cancers occurred in about 0.5% of individuals undergoing CTC examinations.

In 2014, Martin-Lopez et al published a meta-analysis that included 9 studies of CRC screening.³ Studies conducted for the diagnosis of CRC or in elderly, high-risk, or symptomatic patients were excluded. The overall per-patient pooled sensitivity and specificity of CTC were 66.8% (95% CI, 62.7% to 70.8%) and 80.3% (95% CI, 77.7% to 82.8%), respectively. For colonoscopy, the pooled sensitivity was 92.5% (95% CI, 89.0% to 95%) and pooled specificity was 73.2% (95% CI, 67.7% to 78.1%). In the subgroup with larger lesions, the diagnostic accuracy of both approaches was more similar. For lesions 10 mm or larger, CTC had a pooled sensitivity of 91.2% (95% CI, 86.5% to 94.6%) and a specificity of 87.3% (95% CI, 86.2% to 88.3%). The pooled sensitivity of colonoscopy for lesions 10 mm or larger was 92.9% (95% CI, 86.0% to 97.1%) and the specificity was 91.3% (95% CI, 89.9% to 92.5%).

**Randomized Controlled Trials**
One of the largest studies of a screening population, the American College of Radiology Imaging Network (ACRIN) trial, was published by Johnson et al in 2008.⁴ Patients underwent CTC
prior to standard colonoscopy. The study used 16- to 64-row detector computed tomography scanners, stool-tagging techniques, and minimum training standards for interpreters of the test. A total of 2600 individuals were enrolled, and data were available for 2531 (97%) of them. The results of this trial showed 90% sensitivity of CTC for polyps 10 mm or larger and 86% specificity; positive and negative predictive values were 23% and 99%, respectively. In a follow-up analysis of the ACRIN trial, Fidler et al (2014) demonstrated that CTC had similar sensitivity and specificity in the detection of nonpolypoid adenomas.

More recently, several large RCTs have compared the diagnostic accuracy of CTC with a different method of CRC screening. In the IJspeert et al (2016) study, 8844 individuals were invited to be screened, and 2258 (26%) agreed to participate. This included 982 (34%) of 2920 randomized to CTC and 1276 (22%) of 5924 randomized to standard colonoscopy. The analysis focused on detection of high-risk sessile serrated polyps (SSPs). SSPs were detected more often in colonoscopy examinations (n=55 [4.3%]) than in CTC examinations (n=8 [0.8%]). For the outcome of all SSPs (high and low risk), significantly more were detected with colonoscopy (n=83 [6.5%]) than with CTC (n=21 [2.1%]; p<0.001). Adverse events were not discussed.

Regge et al (2017) reported on a controlled trial in which 5412 individuals were randomized to CTC (n=2674) or flexible sigmoidoscopy (n=2738). The detection rate for advanced adenomas did not differ significantly between groups (p=0.52). Detection rates were 133 (5.1%) in the CTC group and 127 (4.7%) in the flexible sigmoidoscopy group. Ten CRCs were identified in the CTC group and 9 in the flexible sigmoidoscopy group. No serious adverse events were reported.

Clinical Utility
There is no direct evidence that evaluates the impact of CTC on health outcomes compared with optical colonoscopy. Modeling studies, generally done as part of cost-effectiveness analyses, can provide insights into the health outcome benefits of CTC and provide relevant data on cost-effectiveness.

A 2009 TEC Special Report provided a critical appraisal of cost-effectiveness analyses of CTC that informs this review. Seven published studies were selected. Two studies completely simulated assumptions that are consistent with the current diagnostic capability of CTC and recommended practice guidelines. In the 2009 review by Zauber et al, colonoscopy was slightly more effective and was less expensive than CTC. This was based on a model using 1000 individuals who were 65 years old. Despite a somewhat lower per procedure cost, the strategy using CTC was more expensive because CTC was performed every 5 years (vs every 10 years for optical colonography), and patients with polyps 6 mm or larger were referred for optical colonoscopy for polyp removal. In this model, the payment for colonoscopy without polypectomy was $500 and for CTC was $488. In the 2008 review by Scherer et al, the model was based on 1000 individuals aged 50 years. In this analysis, the only model for CTC that was more effective than every 10-year optical colonoscopy was CTC every 5 years for removal of polyps 6 mm or larger. Using these assumptions, this CTC approach saved 118.5 lives compared with 116.8 for every 10-year optical colonoscopy; the costs of the 2 approaches were $2.95 million and $1.86 million, respectively. In this analysis, the costs of each procedure were comparable—$523 for CTC compared with $522 for optical colonoscopy without polypectomy. Thus, outcomes using CTC were comparable with those for optical colonoscopy, yet the CTC strategy was costlier. In this study, a sensitivity analysis showed that when the cost of CTC was 36% that of colonoscopy, CTC became less expensive.

Another cost-effectiveness analysis of several colon cancer screening techniques by Heitman et al (2010) compared several colon cancer screening techniques. This analysis indicated that CTC was similar in effectiveness to several other established screening techniques but was more expensive and was, therefore, an undesirable strategy.
Lansdorp-Vogelaar et al (2011) conducted a systematic review of cost-effectiveness studies of colon cancer screening techniques and found 55 publications relating to 32 unique cost-effectiveness models. CTC was evaluated in 8 models. Although CTC was deemed cost-effective compared with no screening, it was both more expensive and less effective based on the established screening strategies in five of the analyses. Reviewers found 1 study in which CTC would be the recommended screening strategy at a cost per life-year gained of less than $50,000.

In general, in these cost-effectiveness analyses, colonoscopy was the more effective screening test. CTC was a dominant option (more effective and less costly) only in the 2008 study that added CTC’s benefit of detection of an aortic aneurysm and extracolonic cancers. This study also incorporated long-term radiation effects. This benefit of detecting extracolonic disease was calculated to account for up to 20% of the total health benefit achieved. Most of the benefit was estimated to be from early detection of aortic aneurysms. Screening for an aneurysm using ultrasound has been demonstrated to be effective in older (i.e., age ≥65 years) men and has been recommended for older male smokers. Screening for the other cancers assumed to be detected has not been shown to be effective. Further research is needed to bolster the data supporting the benefit of CTC specific to aortic aneurysm, especially in older people, and extracolonic cancer detection, as well as the costs and potential health risks of false-positive findings.

Hanly et al published a systematic review of cost-effectiveness studies of CTC in 2012. They concluded that CTC is cost-effective compared with no screening. They could not reach a conclusion for their comparison with colonoscopy, due to differences in study parameters and assumptions. They noted that in early studies, colonoscopy dominated CTC (i.e., it was both more effective and less expensive). More recent studies have had variable results, dependent on the threshold for colonoscopy referral and whether the costs and effects of acting on extracolonic findings seen on CTC are taken into account.

Due to differing assumptions, current studies and practice guidelines vary in their evaluations of the comparative costs and effects of CTC and colonoscopy. Overall benefit without consideration of costs appears to be similar between the tests regarding colon cancer prevention. Most studies did not consider the potential benefits of aortic aneurysm detection and extracolonic cancer detection. CTC was generally more expensive and, in many studies, less effective as a screening strategy than colonoscopy, and in other studies only slightly more effective.

Impact of CTC on Colon Cancer Screening Adherence
Compliance with recommendations for optical colonoscopy is suboptimal, with the most recent data (2013) suggesting a screening rate of about 60% (in the prior 10 years) among people ages 50 to 75. CTC has been proposed as an alternative colon cancer screening technique that may improve patient compliance compared with optical colonoscopy. A literature survey of studies that attempted to determine whether the availability of CTC would improve population screening rates found survey studies, patient satisfaction studies, and focus group studies. It is unclear how such studies provide a sufficient base of evidence to demonstrate that population adherence to colon cancer screening would improve through CTC.

Stoop et al published an RCT in 2012 that evaluated the impact of CTC on colon cancer screening rates. This trial was performed in the Netherlands, and members of the general population ages 50 to 75 years were randomized to an invitation for CTC or optical colonoscopy. The CTC protocol included a noncathartic preparation, consisting of iodinated contrast agent given the day before the exam and 1.5 hours before the exam, in conjunction with a low fiber diet. The participation rate in the CTC group was 34% (982/2920) compared with a rate of 22% (1276/5924) in the optical colonoscopy group (p<0.001). The diagnostic yield per participant of advanced polyps was higher in the optical colonoscopy group, at 8.7 of 100 participants compared with 6.1 of 100 participants for CTC (p=0.02). However, the diagnostic
yield of advanced neoplasia per invitee was similar, at 2.1 of 100 invitees for CTC and 1.9 of 100 invitees for optical colonoscopy (p=0.56). These data would indicate that the increased participation rates with CTC offset the advantages of optical colonoscopy and that overall outcomes would likely be similar between strategies. It is not known whether the same participation rates would be achieved if CTC employed a cathartic preparation or whether the different preparation regimens affect participation rates.

Section Summary: Computed Tomography Colonography for Colon Cancer Screening

There is some variability in the diagnostic accuracy of CTC in the literature; this is likely due to the improvement in technical reliability over time. The most recent studies have reported that the diagnostic accuracy for CTC is high and in the same range as optical colonoscopy for polyps greater than 10 mm.

There are no long-term comparative studies that have directly reported on outcomes of CTC vs optical colonoscopy. The determination of comparative outcomes of CTC and optical colonoscopy is complex, due to the differing patterns of follow-up associated with each strategy. Studies of cost-effectiveness have modeled outcomes of the 2 procedures and generally concluded that outcomes are similar, or that optical colonoscopy results in better outcomes. These analyses assumed equal participation rates between strategies.

At least 1 well-conducted RCT indicated that CRC screening participation rates are improved with CTC in comparison with optical colonoscopy. The improved screening rate may offset, or even outweigh, any benefit of optical colonoscopy on outcomes. However, the available study used a noncathartic preparation, and it is not certain that similar screening rates would be achieved with a cathartic preparation.

CTC for Colon Cancer Diagnosis

CTC has not generally been employed as a test to identify disease in persons with positive cancer screening tests or symptoms, because compared with screening settings, the expected probability of disease is much higher. Findings on CTC require confirmation with colonoscopy; thus it is not rational to use a noninvasive test if the probability of needing a confirmatory invasive test is high.

However, several studies have evaluated the role of CTC in the diagnosis of CRC in patients who have had symptoms or positive findings on other screening modalities (e.g., fecal occult blood testing [FOBT]). In 2014, Plumb et al published a systematic review and meta-analysis of studies evaluating the performance of CTC for the diagnosis of colon cancer among subjects with positive FOBT. FOBT is a recommended screening technique for CRC; positive tests are typically followed with colonoscopy. In this meta-analysis, reviewers included only studies that used CTC in the evaluation of patients who had had a positive FOBT and compared colonography results with a reference test, conventional colonoscopy, segmental unblinded colonoscopy, or surgery with subsequent histopathology. Five articles were analyzed, representing 4 studies with 622 patients. Pooled per patient sensitivity and specificity for adenomas 6 mm or larger or CRC were 88.8% (95% CI, 83.6% to 92.5%) and 75.4% (95% CI, 58.6% to 86.8%), respectively. Reviewers commented that data were limited on CTC for patients with a positive FOBT (only 4 studies) and that, based on the available evidence, CTC has a reasonably high sensitivity for detecting adenomas 6 mm or larger but a relatively low specificity.

Also in 2014, Plumb et al published findings of a retrospective study comparing results from CTC with optical colonoscopy in patients evaluated at a single center who were indicated for CRC diagnostic assessment because of a positive FOBT. This study was not included in the Plumb 2014 review (described above). Based on the institutional protocol, optical colonoscopy was preferred for individuals with positive FOBT; however, CTC was substituted if the subject was unable to complete colonoscopic bowel preparation safely, was too frail or immobile to undergo colonoscopy (although potentially fit for necessary treatment), had another contraindication to colonoscopy, or had an incomplete colonoscopy. The study analyzed 2731...
FOBT-positive patients screened with CTC as their first screening test. Of these, 1027 (37.6%) had CRC or polyps suspected (95% CI, 33.8% to 41.4%), and 911 underwent confirmatory testing. One hundred twenty-four (4.5%) were found to have CRC and 533 (19.5%) were found to have polyps, for an overall CRC- or polyp-detection rate of 24.1% (95% CI, 21.5% to 24.1%). The positive predictive value for CRC or polyps was 72.1% (95% CI, 66.6% to 77.6%). Colonoscopy data were available for 72,817 FOBT-positive patients who underwent colonoscopy as an initial screening test, among whom 9.0% had CRC, and 50.6% had polyps. The authors attributed the difference in CRC and polyp rates between the groups to underlying differences in risk between those referred for CTC and potential biases in the interpretation of screening guidelines.

Several studies have evaluated the role of CTC for patients with symptoms suggestive of CRC. In 2013, Atkin et al reported results from an unblinded RCT comparing colonoscopy with CTC in the evaluation of patients who had symptoms suggestive of CRC. Given the challenges of conducting a trial that would be adequately powered to detect small differences between CTC and colonoscopy in CRC- and large polyp-detection, the authors used rates of the need for additional evaluation after CTC as a primary outcome, on the assumption that such rates would strongly affect the evaluation of the benefits and costs of the procedure. The study randomized patients ages 55 or older with symptoms suggestive of CRC in a 2:1 fashion to colonoscopy or CTC. Both colonoscopy and CTC procedures were conducted with a full bowel preparation. The trial’s primary outcome was the proportion of patients who had additional colonic investigation, defined as any subsequent examination of the colon until diagnosis (usually histologic confirmation of a cancer or polyp) or until a patient was referred back to his or her physician. Additional diagnostic evaluation of the colon was required in 160 (30.0%) of 533 of those assigned to CTC compared with 86 (8.2%) of 1047 of those assigned to colonoscopy (p<0.001). The overall detection rate for CRC or large polyps did not differ between the groups (relative risk, 0.95; 95% CI, 0.70 to 1.27; p=0.69).

Simons et al (2013) evaluated the false-negative rate and sensitivity of CTC for CRC among patients who presented with symptoms of CRC. The authors included 1855 consecutive patients who underwent CTC at a single center. These data were linked to a comprehensive population-based cancer registry to determine if patients were diagnosed with CRC in the 2 years after their CTC. Fifty-three patients were diagnosed with CRC, of whom 40 patients had had suspected CRC, 5 diagnosed with large polyps that appeared malignant on histology, and 5 diagnosed with an indeterminate mass on CTC. Two patients who developed cancer had not been diagnosed on CTC, and 1 patient who developed cancer had had an incomplete colonography. The overall sensitivity of CTC was 94.3% (95% CI, 88% to 100%).

Section Summary: CTC for Colon Cancer Diagnosis
There are a relatively small number of studies of CTC for diagnosis of CRC in patients with a positive screening test or with symptoms of CRC. A systematic review of CTC studies in patients with a positive FOBT identified only 4 studies and found a reasonably high sensitivity for detecting adenomas 6 mm or larger but a relatively low specificity. An RCT comparing CTC with colonoscopy in symptomatic patients found a significantly greater need for additional evaluation after CTC compared with colonoscopy. Because the prevalence of disease is much higher in patients with positive screening tests or symptoms of CRC, going directly to colonoscopy is usually the preferred clinical strategy. Additional studies are needed to determine with certainty the diagnostic accuracy of CTC for diagnosis of CRC; however, for patients unable to undergo a colonoscopy, based on the available evidence, CTC may be a reasonable option.

Summary of Evidence
For individuals who are asymptomatic and undergoing CRC screening who receive CTC, the evidence includes diagnostic accuracy studies, systematic reviews of diagnostic accuracy studies, and modeling studies on clinical utility. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. The available evidence supports the conclusion that the diagnostic accuracy of CTC is in the same range as
optical colonoscopy, with a moderate-to-high sensitivity and a high specificity for the detection of larger polyps and CRC. As a result, screening with CTC may provide similar diagnostic results to screening using conventional optical colonoscopy. Most modeling studies have reported that the overall health outcome benefits of a strategy that uses optical colonoscopy likely exceed the benefits of a strategy using CTC. However, these analyses assume equal participation rates in screening between the strategies. Participation in screening may be higher with CTC than with optical colonoscopy, and this may ameliorate or offset any improved outcomes associated with optical colonoscopy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have positive CRC screening tests or signs or symptoms of CRC who receive CTC, the evidence includes a randomized controlled trial, diagnostic accuracy studies, and a systematic review of diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. Using CTC on patients with suspected disease might be an inefficient testing strategy because CTC findings need to be confirmed with conventional colonoscopy. There are a small number of studies on CTC for diagnosis of CRC in patients with a positive screening test or with symptoms of CRC, and thus the diagnostic accuracy cannot be determined with certainty. Studies of patients with a positive fecal occult blood test have suggested a reasonably high sensitivity for detection of adenomas 6 mm or larger but a relatively low specificity. There are fewer studies of patients with CRC symptoms; the randomized controlled trial found that significantly more patients required additional evaluation after CTC than after conventional colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

American College of Physicians
In 2012, the American College of Physicians (ACP) updated its guidelines for colorectal cancer (CRC) screening. ACP made the following recommendations on colon cancer screening:

“ACP recommends using a stool based test, flexible sigmoidoscopy, or optical colonoscopy as a screening test in patients who are at average risk. ACP recommends using optical colonoscopy as a screening test in patients who are at high risk. Clinicians should select the test based on the benefits and harms of the screening test, availability of the screening test, and patient preferences.”

The guidelines further noted that computed tomography colonography (CTC) is an option for screening average-risk patients older than 50 years.

American Cancer Society et al
In 2008, the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (ACR) released joint guidelines on CRC screening. These guidelines recognized 2 types of screening tests: colon cancer prevention and cancer detection. Colon cancer prevention tests detect both early cancer and adenomatous polyps. The cancer prevention options recommended were flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, double-contrast barium enema every 5 years, or CTC every 5 years. For cancer detection, 3 types of fecal screening tests were supported: annual guaiac-based tests, annual fecal immunochemical tests, and stool DNA tests. The guidelines endorsed colon cancer prevention as the “primary goal of [colorectal cancer] screening” where resources and patient acceptance permit.

A 2006 statement by the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer on colonoscopy surveillance after cancer resection recommended that, in patients with obstructing colon cancers, CTC with intravenous contrast may be used to detect neoplasms in the proximal colon.
American College of Gastroenterology

In 2017, the American College of Gastroenterology published recommendations of the U.S. Multi-Society Task Force of Colorectal Cancer made up of expert gastroenterologists from the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. The panel recommended CRC screening beginning at age 50 with adjustments based on race and family history using a ranked-tiered CRC screening approach in Table 1. Considerations for recommending the tiered system of current CRC screening tests included performance, cost, patient acceptance, and the lack of randomized trial results that directly compare the effects of different tests on CRC incidence or mortality.

<table>
<thead>
<tr>
<th>Tier</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>• Colonoscopy every 10 y&lt;br&gt;• Annual fecal immunochemical test</td>
</tr>
<tr>
<td>Tier 2</td>
<td>• Computed tomography colonography every 5 y&lt;br&gt;• Fecal immunochemical test-fecal DNA every 3 y&lt;br&gt;• Flexible sigmoidoscopy every 10 y (or every 5 y)</td>
</tr>
<tr>
<td>Tier 3</td>
<td>• Capsule colonoscopy every 5 y</td>
</tr>
<tr>
<td></td>
<td><strong>Available tests not currently recommended</strong></td>
</tr>
<tr>
<td></td>
<td>• Septin 9</td>
</tr>
</tbody>
</table>

In 2012, the American College of Gastroenterology, along with the American Gastroenterological Association Institute and the American Society for Gastrointestinal Endoscopy, updated their 2006 guidelines on colonoscopy surveillance after polypectomy. The guidelines made the following statement on CTC and other newer colonic imaging technologies: “The role of new endoscopic technologies has not been studied in surveillance cohorts, although there are ongoing studies of CT colonography.... At this point, these technologies do not have an impact on surveillance intervals.”

In 2009, the American College of Gastroenterology issued guidelines for CRC screening. It recommended colonoscopy every 10 years, beginning at age 50, as the preferred screening strategy for the general population. Patients who declined colonoscopy or for whom colonoscopy would not be feasible should be offered other screenings such as flexible sigmoidoscopy every 5 to 10 years, CTC every 5 years, and an annual fecal immunochemical test.

European Society of Gastrointestinal Endoscopy et al

In 2014, the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) issued guidelines on the use of CTC. These guidelines recommended CTC as outlined in Table 2.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESGE/ESGAR recommend CTC as the radiologic examination of choice for the diagnosis of colorectal neoplasia</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR do not recommend barium enema in this setting</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR recommend CTC, preferably the same or next day, if colonoscopy is incomplete. Delay of CTC should be considered following endoscopic resection. In the case of obstructing colorectal cancer, preoperative contrast-enhanced CTC may also allow location or staging of malignant lesions.</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>When endoscopy is contraindicated or not possible, ESGE/ESGAR recommend as an acceptable and equally sensitive alternative for patients with symptoms suggestive of colorectal cancer</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>ESGE/ESGAR do not recommend CTC as a primary test for population screening or in individuals with a positive first-degree family history of CRC. However, it may be proposed as a CRC screening test on an individual basis</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Recommendation: Providing the screenee is adequately informed about test characteristics, benefits, and risks.

CRC: Colorectal Cancer; CTC: Computed Tomography Colonography; QOE: Quality Of Evidence; SOR: Strength Of Recommendation.

**American College of Radiology**

In 2014, ACR updated its appropriateness criteria on imaging tests for CRC screening, which included the guidelines related to CTC listed in Table 3.28

### Table 3. Appropriateness Criteria for Colorectal Cancer Screening

<table>
<thead>
<tr>
<th>Variant</th>
<th>Procedure</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average-risk individual: age ≥50 y</td>
<td>CTC every 5 y after negative screen</td>
<td>9</td>
</tr>
<tr>
<td>Average-risk individual after positive fecal occult blood test, indicating a relative elevation in risk</td>
<td>CTC</td>
<td>9</td>
</tr>
<tr>
<td>Average-, moderate-, or high-risk individual after incomplete colonoscopy</td>
<td>CTC</td>
<td>9</td>
</tr>
<tr>
<td>Moderate-risk individual: personal history of adenoma or carcinoma or first-degree family history of cancer or adenoma</td>
<td>CTC every 5 y after negative screen</td>
<td>9</td>
</tr>
<tr>
<td>High-risk individual: hereditary nonpolyposis colorectal cancer</td>
<td>CTC</td>
<td>3a</td>
</tr>
<tr>
<td>High-risk individual: ulcerative colitis or Crohn colitis</td>
<td>CTC</td>
<td>3a</td>
</tr>
</tbody>
</table>

American College of Radiology rating scale: 1-3: usually not appropriate; 4-6: may be appropriate; 7-9: usually appropriate.

CTC: computed tomography colonography.

a Colonoscopy is the preferred procedure.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force (USPSTF) updated its recommendations on CRC screening in 2016.29 The recommendations included the following:

*Adults 50 to 75 years old:*

“The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years.” (Grade A)

*Adults 76 to 85 years old:*

“The decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient’s overall health and prior screening history.

- Adults in this age group who have never been screened for colorectal cancer are more likely to benefit.
- Screening would be most appropriate among adults who 1) are healthy enough to undergo treatment if colorectal cancer is detected and 2) do not have comorbid conditions that would significantly limit their life expectancy.” (Grade C)

In a section on clinical considerations, USPSTF stated that evidence on CTC is limited to studies on test characteristics and that CTC can result in incidental extracolonic findings. USPSTF also noted indirect harms resulting from standard colonoscopy performed for positive CTC findings. Previously, in the 2008 version of USPSTF recommendation on CRC screening, the evidence for CTC was judged to be insufficient to evaluate the benefits and harms (i.e., I rating). The conclusion was based on concerns about potential harms of radiation exposure and potential for harm due to the evaluation of extracolonic findings. The 2016 USPSTF recommendations do not include a specific statement on screening with CTC.

**Medicare National Coverage**

In 2009, the Centers for Medicare & Medicaid Services published a decision memo on CTC screening, which stated: “The evidence is inadequate to conclude that CTC colonography is an appropriate colorectal cancer screening test under §1861(pp) (1) of the Social Security Act. CTC colonography for colorectal cancer screening remains noncovered.”31
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCTNo.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Comparison Between Faecal Occult Blood Test (FOBT), Computed Tomographic Colonography (CTC) With Computer Aided Diagnosis (CAD) and Colonoscopy as a Primary Screening Test for Colorectal Cancer</td>
<td>14,000</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: National Clinical Trial.

References


Documentation for Clinical Review

Please provide the following documentation (if/when requested):
- History and physical and/or consultation notes including:
  - Anesthesiologist pre-operative assessment
  - Reason a conventional colonoscopy is not indicated

Post Service
- Procedure report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>74261</td>
<td>Computer tomographic (CT) colonography, diagnostic, including image post processing; without contrast material</td>
</tr>
<tr>
<td></td>
<td>74262</td>
<td>Computer tomographic (CT) colonography, diagnostic, including image post processing; with contrast material(s) including non-contrast images, if performed</td>
</tr>
<tr>
<td></td>
<td>74263</td>
<td>Computer tomographic (CT) colonography, screening, including image post processing</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>BD2400Z</td>
<td>Computerized Tomography (CTScan) of Colon using High Osmolar Contrast, Unenhanced and Enhanced</td>
</tr>
<tr>
<td></td>
<td>BD240ZZ</td>
<td>Computerized Tomography (CTScan) of Colon using High Osmolar Contrast</td>
</tr>
<tr>
<td></td>
<td>BD2410Z</td>
<td>Computerized Tomography (CTScan) of Colon using Low Osmolar Contrast, Unenhanced and Enhanced</td>
</tr>
<tr>
<td></td>
<td>BD241ZZ</td>
<td>Computerized Tomography (CTScan) of Colon using Low Osmolar Contrast</td>
</tr>
<tr>
<td></td>
<td>BD24Y0Z</td>
<td>Computerized Tomography (CTScan) of Colon using Other Contrast, Unenhanced and Enhanced</td>
</tr>
<tr>
<td></td>
<td>BD24YZZ</td>
<td>Computerized Tomography (CTScan) of Colon using Other Contrast</td>
</tr>
<tr>
<td></td>
<td>BD24ZZZ</td>
<td>Computerized Tomography (CTScan) of Colon</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All Diagnoses</td>
<td>All Diagnoses</td>
</tr>
</tbody>
</table>
Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/2003</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>06/01/2004</td>
<td>Policy Review</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>12/07/2006</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>05/08/2009</td>
<td>Policy Title Revision, Medically Necessary criteria added</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>06/26/2009</td>
<td>Policy Revision</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>01/15/2010</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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<td>04/01/2011</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>09/30/2014</td>
<td>Policy title change from CT Colonography (Virtual Colonoscopy) Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/01/2016</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.